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BACKGROUND: Rigorous verification, validation, and credibility (VV&C) processes are imperative to ensure that models and simulations (M&S) are sufficiently reliable to address issues within their intended scope. The NASA standard for M&S, NASA-STD-7009 (7009) [1] was a resultant outcome of the Columbia Accident Investigation Board (CAIB) to ensure M&S are developed, applied, and interpreted appropriately for making decisions that may impact crew or mission safety. Because the 7009 focuses on engineering systems, a NASA-STD-7009 Guidance Document is being developed to augment the 7009 and provide information, tools, and techniques applicable to the probabilistic and deterministic biological M&S more prevalent in human health and performance (HHP) and space biomedical research and operations. Cumulative experiences from both projects as well as endeavors to apply the 7009 to other HHP M&S have culminated in the generation of a NASA-STD-7009 Guidance Document.

METHODS: The Integrated Medical Model (IMM) project and Digital Astronaut Project (DAP) have invested substantial effort to adapt NASA-STD-7009 VV&C processes to achieve the CAIB goals listed above. As part of these efforts, IMM and DAP projects work closely with end-users, such as space life science researchers, NASA flight surgeons, and space program risk managers, to establish useful VV&C information, tools, and techniques that facilitate comprehensive understanding and appropriate use of these M&S. Cumulative experiences from both projects as well as endeavors to apply the 7009 to other HHP M&S have culminated in the generation of a NASA-STD-7009 Guidance Document.

RESULTS: The NASA-STD-7009 Guidance Document contains illustrative examples of various types and applications of biological M&S that provide insight into the context of HHP and space biomedical research and operations M&S. It details how to quantitatively evaluate M&S including establishing appropriate M&S credibility thresholds. A weighting process is introduced for the different credibility factors, the use of which has increased end user fidelity and allowed better conception of M&S status for both IMM and DAP projects. Detail regarding peer and technical review is expanded in the NASA-STD-7009 Guidance Document with listed recommendation strategies to utilize for organizing and executing the process. While improving the VV&C processes for the end-users listed above, application of the information, tools, and techniques in the NASA-STD-7009 Guidance Document by IMM and DAP projects to quantify the credibility of biomedical models has also received considerable attention from the medical modeling community. Consequently, FDA and NIH are adapting the methods developed by the IMM and DAP projects as the basis for new standards for vetting computational models that are intended to be applied in individualized health care.

CONCLUSIONS: Augmenting the NASA-STD-7009 with the NASA-STD-7009 Guidance Document will facilitate applying 7009 recommendations and requirements for M&S encompassing HHP and space biomedical research and operations. The IMM and DAP projects have demonstrated practical application of the principles outlined in the NASA-STD-7009 Guidance Document and have provided probabilistic and deterministic models for medical event prediction, exercise physiology, bone physiology, crew and mission risk management, and other applications. Methods and principles established here have also generated substantial interest by the FDA and NIH to develop similar standards to guide the larger medical operations and research community.

REFERENCES: